Exhibit A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION

MDL NO. 2924
20-MD-2924

JUDGE ROBIN L. ROSENBERG
MAGISTRATE JUDGE BRUCE E. REINHART

_____/

ORDER GRANTING GENERIC MANUFACTUERS' AND REPACKAGERS' RULE 12 MOTION TO DISMISS ON THE GROUND OF PREEMPTION

This matter is before the Court on Defendants Generic Manufacturers' ("Generic Manufacturer Defendants") and Repackagers' ("Repackager Defendants") (collectively "Defendants") Rule 12 Motion to Dismiss on the Ground of Preemption ("Motion to Dismiss"). DE 1582. The Court held a hearing on the Motion to Dismiss on December 15, 2020 ("the Hearing"). The Court has carefully considered the Motion to Dismiss, Plaintiffs' Opposition thereto [DE 1978; DE 2010-1],[1] Defendants' Reply [DE 2133], Plaintiffs' Notice of Supplemental Authority [DE 2488], the arguments that the parties made during the Hearing, and the record and is otherwise fully advised in the premises. For the reasons set forth below, the Motion to Dismiss is **GRANTED**.

[1] Plaintiffs filed an Opposition at DE 1978 that contains a redaction and filed an unredacted version of the Opposition at DE 2010-1. Citations to the Opposition throughout this Order are to the unredacted version.

I. Factual Background[2]

This case concerns the pharmaceutical product Zantac and its generic forms, which are widely sold as heartburn and gastric treatments. The molecule in question—ranitidine—is the active ingredient in both Zantac and its generic forms.

Zantac has been sold since the early 1980's, first by prescription and later as an over-the-counter ("OTC") medication. In 1983, the U.S. Food and Drug Administration ("FDA") approved the sale of prescription Zantac. MPIC ¶¶ 226, 231, 432. GlaxoSmithKline ("GSK") first developed and patented Zantac. *Id.* ¶ 230. Zantac was a blockbuster – the first prescription drug in history to reach $1 billion in sales. *Id.* ¶ 231.

GSK entered into a joint venture with Warner-Lambert in 1993 to develop an OTC form of Zantac. *Id.* ¶ 233. Beginning in 1995, the FDA approved the sale of various forms of OTC Zantac. *Id.* ¶¶ 233, 237. The joint venture between GSK and Warner-Lambert ended in 1998, with Warner-Lambert retaining control over the sale of OTC Zantac in the United States and GSK retaining control over the sale of prescription Zantac in the United States. *Id.* ¶ 234. Pfizer acquired Warner-Lambert in 2000 and took control of the sale of OTC Zantac in the United States. *Id.* ¶ 235. The right to sell OTC Zantac in the United States later passed to Boehringer Ingelheim Pharmaceuticals and then to Sanofi. *Id.* ¶¶ 239-40, 242-44. When the patents on prescription and OTC Zantac expired, numerous generic drug manufacturers began to produce generic ranitidine products in prescription and OTC forms. *Id.* ¶¶ 249-51.

[2] A court must accept a plaintiff's factual allegations as true at the motion–to–dismiss stage. *West v. Warden*, 869 F.3d 1289, 1296 (11th Cir. 2017) ("When considering a motion to dismiss, we accept as true the facts as set forth in the complaint and draw all reasonable inferences in the plaintiff's favor." (quotation marks omitted)). Plaintiffs have set forth their factual allegations in three "master" complaints: the Master Personal Injury Complaint ("MPIC"), the Consolidated Consumer Class Action Complaint ("CCCAC"), and the Consolidated Third Party Payor Class Complaint ("CTPPCC") (collectively "Master Complaints"). DE 887, 888, 889.

Scientific studies have demonstrated that ranitidine can transform into a cancer-causing molecule called N-nitrosodimethylamine ("NDMA"), which is part of a carcinogenic group of compounds called N-nitrosamines. *Id.* ¶¶ 253, 321, 324, 331. Studies have shown that these compounds increase the risk of cancer in humans and animals. *Id.* ¶¶ 253, 264-72. The FDA, the Environmental Protection Agency, and the International Agency for Research on Cancer consider NDMA to be a probable human carcinogen. *Id.* ¶¶ 254, 258. The FDA has set the acceptable daily intake level for NDMA at 96 nanograms. *Id.* ¶¶ 4, 263.

Valisure LLC and ValisureRX LLC, a pharmacy and testing laboratory, filed a Citizen Petition on September 9, 2019, calling for the recall of all ranitidine products due to high levels of NDMA in the products. *Id.* ¶ 285. The FDA issued a statement on September 13 warning that some ranitidine products may contain NDMA. *Id.* ¶ 286. On November 1, the FDA announced that testing had revealed the presence of NDMA in ranitidine products. *Id.* ¶ 296. The FDA recommended that drug manufacturers recall ranitidine products with NDMA levels above the acceptable daily intake level. *Id.* Six months later, on April 1, 2020, the FDA requested the voluntary withdrawal of all ranitidine products from the market. *Id.* ¶ 301.

II. Procedural Background

After the discovery that ranitidine products may contain NDMA, Plaintiffs across the country began initiating lawsuits related to their purchase and/or use of the products. On February 6, 2020, the United States Judicial Panel on Multidistrict Litigation created this multi-district litigation ("MDL") pursuant to 28 U.S.C. § 1407 for all pretrial purposes and ordered federal lawsuits for personal injury and economic damages from the purchase and/or use of ranitidine products to be transferred to the undersigned. DE 1. Since that time, hundreds of Plaintiffs have filed lawsuits in, or had their lawsuits transferred to, the United States District Court for the

Southern District of Florida. In addition, this Court has created a Census Registry where thousands of claimants who have not filed lawsuits have registered their claims. *See* DE 547.

Plaintiffs filed three Master Complaints on June 22, 2020. DE 887, 888, 889. Plaintiffs contend that the ranitidine molecule is unstable, breaks down into NDMA, and has caused thousands of consumers of ranitidine products to develop various forms of cancer. MPIC ¶¶ 1, 6, 19. Plaintiffs allege that "a single pill of ranitidine can contain quantities of NDMA that are hundreds of times higher" than the FDA's allowable limit. *Id.* ¶ 4. Plaintiffs are pursuing federal claims and state claims under the laws of all 50 U.S. states, Puerto Rico, and the District of Columbia. *See generally* CCCAC. The entities named as defendants are alleged to have designed, manufactured, tested, marketed, distributed, labeled, packaged, handled, stored, and/or sold ranitidine products. MPIC ¶¶ 20, 225.

The Court has entered numerous Pretrial Orders to assist in the management of this MDL. In Pretrial Order # 30, the Court set a case management schedule that is intended to prepare the MDL for the filing of *Daubert* motions on general causation and class certification motions in December 2021. DE 875; *see generally Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). In Pretrial Order # 36, the Court set a schedule for the filing and briefing of motions to dismiss under Federal Rule of Civil Procedure 12 directed to the Master Complaints. DE 1346. Defendants filed the instant Motion to Dismiss pursuant to that schedule.

III. The Master Complaints

Plaintiffs filed three Master Complaints in this MDL: the MPIC, the CCCAC, and the CTPPCC. DE 887, 888, 889. The MPIC raises claims against parties referred to as Generic Manufacturer Defendants that allegedly manufactured generic ranitidine products. MPIC ¶¶ 38-144. The MPIC further raises claims against parties referred to as Repackager Defendants

that allegedly repackaged ranitidine products into different containers and changed "the content on an original manufacturer's label to note the drug [was] distributed or sold under the relabeler's own name," "without manipulating, changing, or affecting the composition or formulation of the drug." *Id.* ¶¶ 211-15. Some of the parties categorized as Generic Manufacturer Defendants are also categorized as Repackager Defendants. *See, e.g.*, *id.* ¶¶ 44, 52. The parties named as Generic Manufacturer Defendants and as Repackager Defendants are not identical among the Master Complaints.

The MPIC contains 15 counts: Strict Products Liability—Failure to Warn, Strict Products Liability—Design Defect, Strict Products Liability—Manufacturing Defect, Negligence—Failure to Warn, Negligence Product Design, Negligent Manufacturing, General Negligence, Negligent Misrepresentation, Breach of Express Warranties, Breach of Implied Warranties, Violation of Consumer Protection and Deceptive Trade Practices Laws, Unjust Enrichment, Loss of Consortium, Survival Actions, and Wrongful Death. Each count is brought against Generic Manufacturer Defendants. All of these counts, other than the Strict Products Liability—Manufacturing Defect and Negligent Manufacturing counts, are also brought against Repackager Defendants.

The CCCAC also raises claims against parties referred to as Generic Manufacturer Defendants and Repackager Defendants. CCCAC ¶¶ 277-357, 416-20. The CCCAC contains 314 counts on behalf of putative nationwide and state classes. The putative nationwide class alleges counts for unjust enrichment, violation of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301, *et seq.* ("MMWA"), and common law fraud. The putative state classes allege counts for negligence, battery, product-liability, breach-of-warranty, consumer-protection, and medical-monitoring causes of action.

The CTPPCC raises claims against parties referred to as Generic Manufacturer Defendants. CTPPCC ¶¶ 46-121. The CTPPCC contains nine counts on behalf of a putative nationwide class of Third Party Payors that allegedly paid for prescription medications for others or, alternatively, on behalf of putative state classes. *Id.* ¶¶ 124, 506, 508. The putative class alleges counts of Breach of Express Warranties, Breach of Implied Warranties, Violation of the MMWA, Fraud, Negligent Misrepresentation and Omission, Violations of State Consumer Protection Laws, Unjust Enrichment, and Negligence.[3]

IV. Summary of the Parties' Arguments

Defendants argue in the Motion to Dismiss that all of Plaintiffs' state-law claims against them, regardless of how labeled and pled, are claims for design defect or failure to warn. The Supreme Court has ruled in two significant opinions—*PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) and *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013)—that such claims against generic drug manufacturers are pre-empted because they cannot remedy design defects or provide additional warnings while remaining in compliance with federal law. The Supreme Court's rulings apply with equal force to repackagers. Therefore, all of the state-law claims against Defendants must be dismissed. And because Plaintiffs' only federal claims against Defendants, for violations of the MMWA, require a valid state-law warranty claim, the MMWA claims must be dismissed as

[3] The Master Complaints also raise claims against parties referred to as Brand-Name Manufacturer Defendants, Distributor Defendants, and Retailer Defendants. Brand-Name Manufacturer Defendants allegedly manufactured brand-name ranitidine products; Distributor Defendants allegedly purchased ranitidine products in bulk and sold them to Retailer Defendants; and Retailer Defendants allegedly sold ranitidine products to consumers. In addition to the claims described above, the CCCAC and the CTPPCC contain counts for violation of the Racketeer Influenced and Corruption Organizations Act, 18 U.S.C. § 1962(c)-(d), against Brand-Name Manufacturer Defendants. Brand-Name Manufacturer, Distributor, and Retailer Defendants have also brought motions to dismiss based on pre-emption that the Court addresses by separate Orders. The Court refers to Brand-Name Manufacturer Defendants and Generic Manufacturer Defendants collectively as "Manufacturer Defendants." The Court refers to all defendants named in this MDL collectively as "named defendants."

well. Additionally, 21 U.S.C. § 379r prohibits Plaintiffs from obtaining damages in the form of refunds for the purchase of OTC ranitidine products.

Plaintiffs respond that none of their state-law claims against Defendants are pre-empted under *Mensing* and *Bartlett*. Their claims are not pre-empted because the claims are based on the fact that ranitidine products were misbranded when sold and on Defendants' failure to take actions that they could have taken while remaining in compliance with federal law. In addition, Repackager Defendants can be held liable under an absolute-liability theory because they profited from the marketing of ranitidine products. And because Plaintiffs' state-law warranty claims are not pre-empted, the MMWA claims are viable as well. Section 379r does not prohibit Plaintiffs from obtaining damages in the form of refunds for the purchase of OTC ranitidine products.

V. Summary of the Court's Rulings

The design-defect and failure-to-warn claims that the Supreme Court ruled in *Mensing* and *Bartlett* are pre-empted as against generic drug manufacturers are pre-empted as against Defendants, regardless of Plaintiffs' allegations that ranitidine products were misbranded. Plaintiffs' claims based on alleged product and labeling defects that Defendants could not independently change while remaining in compliance with federal law are dismissed with prejudice as pre-empted. Because all of Plaintiffs' counts against Defendants in the Master Complaints incorporate such allegations, all counts against Defendants are dismissed. Plaintiffs' claims against Repackager Defendants that rely on absolute liability are dismissed with prejudice. The Court grants Plaintiffs leave to replead claims based on expiration dates, testing, storage and transportation conditions, warning the FDA, manufacturing defects, and the MMWA, as well as to replead their derivative counts. The Court will address § 379r in a forthcoming Order on

Branded Defendants' Rule 12 Partial Motion to Dismiss Plaintiffs' Three Complaints as Preempted by Federal Law.

VI. Standard of Review

Defendants move to dismiss all of the claims against them under Federal Rule of Civil Procedure 12(b)(6) based on the affirmative defense of federal pre-emption. *See* DE 1582 at 8;[4] DE 2499 at 37; *see also Mensing*, 564 U.S. at 619 (describing federal pre-emption as a drug manufacturer's affirmative defense). A court may grant a motion to dismiss a pleading if the pleading fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). A court ruling on a motion to dismiss accepts the well-pled factual allegations as true and views the facts in the light most favorable to the plaintiff. *Jones v. Fransen*, 857 F.3d 843, 850 (11th Cir. 2017). But the court need not accept legal conclusions couched as factual allegations. *Diverse Power, Inc. v. City of LaGrange, Ga.*, 934 F.3d 1270, 1273 (11th Cir. 2019). "Under Rule 12(b)(6), dismissal is proper when, on the basis of a dispositive issue of law, no construction of the factual allegations will support the cause of action." *Allen v. USAA Cas. Ins. Co.*, 790 F.3d 1274, 1278 (11th Cir. 2015) (quotation marks omitted). A "complaint may be dismissed under Rule 12(b)(6) when its own allegations indicate the existence of an affirmative defense, so long as the defense clearly appears on the face of the complaint." *Quiller v. Barclays Am./Credit, Inc.*, 727 F.2d 1067, 1069 (11th Cir. 1984), *aff'd en banc*, 764 F.2d 1400 (11th Cir. 1985).

VII. Analysis

An understanding of the law that applies to drugs approved by the FDA is necessary to understand the arguments that the parties make in briefing the Motion to Dismiss. Before turning to the parties' arguments, the Court discusses key statutes and regulations that govern the FDA's

[4] All page number references herein are to the page numbers generated by CM/ECF in the header of each document.

regulation of drugs. The Court next addresses impossibility pre-emption and significant cases that have addressed impossibility pre-emption in the drug context. The Court then turns to the issues raised in the briefing: misbranding, expiration dates and testing, storage and transportation conditions, warning the FDA, manufacturing defects, the MMWA, absolute liability, derivative counts, and express pre-emption under 21 U.S.C. § 379r. For each issue, the Court reviews the arguments of the parties, any relevant allegations in the Master Complaints, and any additional, issue-specific law before providing the Court's analysis and conclusion on the issue.

A. Federal Regulation of Drug Products

The FDA regulates prescription and OTC drugs under the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. § 301 *et seq.* ("FDCA"). The FDCA provides a process for the FDA to approve a new drug through a new drug application ("NDA") and a process for the FDA to approve a drug that is the same as a previously approved drug through an abbreviated new drug application ("ANDA"). *See* 21 U.S.C. § 355. A drug must have an FDA-approved NDA or ANDA to be introduced into interstate commerce. *Id.* § 355(a).

1. NDAs

An NDA must contain scientific data and other information showing that the new drug is safe and effective and must include proposed labeling. *See id.* § 355(b)(1). The FDCA defines the term "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *Id.* § 321(m). The FDA may approve the NDA only if it finds, among other things, that the new drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling"; that there is "substantial evidence that the drug will have the effect it purports or is represented to have . . . in the proposed labeling"; that the methods and facilities for manufacturing, processing, and

packaging the drug are adequate "to preserve its identity, strength, quality, and purity"; and that the labeling is not "false or misleading in any particular." *Id.* § 355(d). A drug approved under the NDA process, commonly referred to as a "brand-name drug," is "listed" by the FDA as having been "approved for safety and effectiveness." *See id.* § 355(j)(7). Following the approval of its NDA, a brand-name drug has a certain period of exclusivity in the marketplace. *See id.* § 355(j)(5)(F).

2. ANDAs

Subject to that period of exclusivity, a drug manufacturer may seek the approval of a drug that is identical in key respects to a listed drug by filing an ANDA. *See id.* § 355(j); *Bartlett*, 570 U.S. at 477 (explaining that a generic drug may be approved through the ANDA process "provided the generic drug is identical to the already-approved brand-name drug in several key respects"). A drug approved under the ANDA process is commonly referred to as a "generic drug." The ANDA must contain information showing that the generic drug has the same active ingredient(s), route of administration, dosage form, strength, therapeutic effect, and labeling as the listed drug and is "bioequivalent" to the listed drug. 21 U.S.C. § 355(j)(2)(A). With limited exceptions, the FDA may approve the ANDA only if it finds that the generic drug and its proposed labeling are the same as the listed drug and the listed drug's labeling. *See id.* § 355(j)(4); *see also* 21 C.F.R. § 314.94(a)(8)(iii), (iv) ("Labeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for the drug product must be the same as the labeling approved for the reference listed drug . . . ."). One such exception is that the generic drug's proposed labeling "may include differences in expiration date" from the listed drug. 21 C.F.R. § 314.94(a)(8)(iv).

3. Changes to Drugs with Approved NDAs and ANDAs

The FDA also has requirements for when and how a drug manufacturer may change a drug or drug labeling that has an approved NDA or ANDA. *See id.* §§ 314.70, .97(a). These requirements differ depending on the category of change that the manufacturer seeks to make.

A "major change" is

> any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.

Id. § 314.70(b)(1). Such changes include certain labeling changes, changes "in the qualitative or quantitative formulation of the drug product, including inactive ingredients," and changes "in the synthesis or manufacture of the drug substance that may affect the impurity profile and/or the physical, chemical, or biological properties of the drug substance." *Id.* § 314.70(b)(2)(i), (iv), (v). A major change requires a "supplement submission and [FDA] approval prior to distribution of the product made using the change." *Id.* § 314.70(b). This supplement is referred to as a "Prior Approval Supplement." *See In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 923 (6th Cir. 2014).

A "moderate change" is

> any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.

21 C.F.R. § 314.70(c)(1). The process for making a moderate change is commonly called the "changes-being-effected" process or "CBE" process. *See Mensing*, 564 U.S. at 614. A moderate change generally requires a "supplement submission at least 30 days prior to distribution of the drug product made using the change." 21 C.F.R. § 314.70(c). The drug product with the change

may be distributed prior to FDA-approval, but only after the passage of 30 days from the FDA's receipt of the supplement. *Id.* § 314.70(c)(4). This supplement is referred to as a "Changes Being Effected in 30 Days" supplement. *See id.* § 314.70(c)(3).

However, the FDA may designate certain moderate changes that may be made upon the FDA's receipt of the supplement and need not await the passage of 30 days. *Id.* § 314.70(c)(6). Such changes include certain changes "in the labeling to reflect newly acquired information" and "changes in the methods or controls to provide increased assurance that the drug substance or drug product will have the characteristics of identity, strength, quality, purity, or potency that it purports or is represented to possess." *Id.* § 314.70(c)(6)(i), (iii). Where the passage of 30 days is not required, the supplement is referred to as a "Changes Being Effected" supplement. *Id.* § 314.70(c)(3).

Finally, a "minor change" is a change "in the drug substance, drug product, production process, quality controls, equipment, or facilities that ha[s] a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product." *Id.* § 314.70(d)(1). Such a change includes an "extension of an expiration dating period based upon full shelf life data on production batches obtained from" an approved protocol. *Id.* § 314.70(d)(2)(vi). A minor change must be "described in an annual report." *Id.* § 314.70(d).

Despite the availability of these processes to make changes, "generic drug manufacturers have an ongoing federal duty of 'sameness'" that requires "that the warning labels of a brand-name drug and its generic copy must always be the same." *Mensing*, 564 U.S. at 613; *see also* 21 C.F.R. § 314.150(b)(10) (explaining that approval for an ANDA may be withdrawn if the FDA finds that the drug product's labeling "is no longer consistent with that for the listed drug"). Thus, the CBE

process allows "changes to generic drug labels only when a generic drug manufacturer changes its label to match an updated brand-name label or to follow the FDA's instructions." *Mensing*, 564 U.S. at 614.

B. Impossibility Pre-emption

The Supremacy Clause of the U.S. Constitution provides that the laws of the United States "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. "It is basic to this constitutional command that all conflicting state provisions be without effect." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981) (citing *McCulloch v. Maryland*, 17 U.S. 316, 427 (1819)). The pre-emption doctrine is derived from the Supremacy Clause. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992).

Supreme Court caselaw has recognized that state law is pre-empted under the Supremacy Clause in three circumstances. *English v. Gen. Elec. Co.*, 496 U.S. 72, 78 (1990). First, "Congress can define explicitly the extent to which its enactments pre-empt state law." *Id.* Second, "state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively." *Id.* at 79. Third, state law is pre-empted "to the extent that it actually conflicts with federal law . . . where it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* (citation and quotation marks omitted). Three key Supreme Court opinions have addressed impossibility pre-emption—a subset of conflict pre-emption—in the drug context.

1. *Wyeth v. Levine*

In *Wyeth v. Levine*, a consumer of a brand-name drug sued the brand-name drug manufacturer on negligence and strict-liability theories under Vermont law for failure to provide an adequate warning on the drug's labeling. 555 U.S. 555, 559-60 (2009). The Supreme Court held that the consumer's labeling claims were not pre-empted because the CBE process permitted the brand-name drug manufacturer to "unilaterally strengthen" the warning on the labeling, without waiting for FDA approval. *Id.* at 568-69, 571, 573. The Court stated that it could not conclude that it was impossible for the brand-name drug manufacturer to comply with both its federal-law and state-law duties "absent clear evidence that the FDA would not have approved" a labeling change. *Id.* at 571. The brand-name drug manufacturer "offered no such evidence," and the fact that the FDA had previously approved the labeling did "not establish that it would have prohibited such a change." *Id.* at 572-73.

2. *PLIVA, Inc. v. Mensing*

In *PLIVA, Inc. v. Mensing*, consumers of generic drugs sued the generic drug manufacturers under Minnesota and Louisiana tort law for failure to provide adequate warnings on the drugs' labeling. 564 U.S. at 610. The Supreme Court held that the consumers' labeling claims were pre-empted because the generic drug manufacturers could not "independently" change the labeling while remaining in compliance with federal law. *Id.* at 618-20, 623-24. The generic drug manufacturers' "duty of 'sameness'" under federal law required them to use labeling identical to the labeling of the equivalent brand-name drug. *Id.* at 613. Thus, the CBE process was unavailable to the generic drug manufacturers to change labeling absent a change to the brand-name drug's labeling. *Id.* at 614-15. Because any change that the generic drug manufacturers made to the drugs'

labeling to comply with duties arising under state tort law would have violated federal law, the state tort claims were pre-empted. *Id.* at 618, 623-24.

The consumers argued, and the FDA asserted in an amicus brief, that even if the generic drug manufacturers could not have used the CBE process to change the labeling, the manufacturers could have "asked the FDA for help" by proposing a labeling change to the FDA. *Id.* at 616, 619. The consumers further argued that their state-law claims would not be pre-empted unless the generic drug manufacturers demonstrated that the FDA would have rejected a proposed labeling change. *Id.* at 620. The generic drug manufacturers conceded that they could have asked the FDA for help. *Id.* at 619.

The Supreme Court rejected the argument that the ability to ask the FDA for help defeated impossibility pre-emption. *Id.* at 620-21. The Court stated that the "question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Id.* at 620 (citing *Wyeth*, 555 U.S. at 573). "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 623-24. Asking the FDA for help "would have started a Mouse Trap game" that eventually may have led to a labeling change, "depending on the actions of the FDA and the brand-name manufacturer." *Id.* at 619-20. But, the Court stated, pre-emption analysis that was dependent on what a third party or the federal government might do would render impossibility pre-emption "all but meaningless." *Id.* at 620-21 ("If these conjectures suffice to prevent federal and state law from conflicting for Supremacy Clause purposes, it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force.").

3. *Mutual Pharmaceutical Co. v. Bartlett*

In *Mutual Pharmaceutical Co. v. Bartlett*, a consumer of a generic drug brought a design-defect claim under New Hampshire law against a generic drug manufacturer for failure to ensure that the drug was reasonably safe. 570 U.S. at 475. Under New Hampshire law, a drug manufacturer could satisfy its duty to ensure that its drug was reasonably safe "either by changing a drug's design or by changing its labeling." *Id.* at 482, 492. However, because the generic drug manufacturer was unable to change the drug's composition "as a matter of both federal law and basic chemistry," the only way for the manufacturer to fulfill its state-law duty and "escape liability" was by changing the labeling. *Id.* at 475, 483-84 (citing 21 U.S.C. § 355(j) for the proposition that "the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based"). The Supreme Court concluded that, under *Mensing*, federal law prohibited the generic drug manufacturer "from taking the remedial action required to avoid liability" under state law, that is, changing the labeling, and therefore the consumer's design-defect claim was pre-empted. *Id.* at 475, 486-87 (citing *Mensing*, 564 U.S. 604).

The First Circuit Court of Appeals had ruled that the generic drug manufacturer could comply with both federal and state law by removing the drug from the market. *Id.* at 475, 479. The Supreme Court stated that this was "no solution" because adopting this "stop-selling rationale would render impossibility pre-emption a dead letter and work a revolution in th[e] Court's pre-emption case law." *Id.* at 475, 488-90 (rejecting the stop-selling rationale as "incompatible" with pre-emption jurisprudence because, in "every instance in which the Court has found impossibility pre-emption, the 'direct conflict' between federal- and state-law duties could easily have been avoided if the regulated actor had simply ceased acting"). Pre-emption caselaw

"presume[s] that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." *Id.* at 488.

4. Application of *Mensing* and *Bartlett*

Based on the *Mensing* and *Bartlett* opinions, federal courts have held that numerous categories of claims against generic drug manufacturers are pre-empted, even where plaintiffs do not couch their claims as design defect or failure to warn. For example, courts have held that claims against generic drug manufacturers for failure to communicate information to consumers or medical providers, where the manufacturers of the listed brand-name drugs have not done so, are pre-empted. *See, e.g.*, *In re Darvocet*, 756 F.3d at 932-33 (concluding that a claim that generic drug manufacturers should have sent letters explaining safety risks to medical providers was pre-empted because, "if generic drug manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly misleading" (quotation marks omitted)); *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 474-75 (5th Cir. 2014) (concluding that a claim that generic drug manufacturers should have communicated information consistent with the brand-name drug labeling was pre-empted because "the duty of sameness prohibits the generic manufacturers from taking such action unilaterally, they are dependent on brand-names taking the lead" (quotation omitted)); *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) (concluding that a claim that generic drug manufacturers should have communicated that a labeling change had been made was pre-empted because the manufacturers "were not at liberty" to communicate such information where "no brand-name manufacturer sent a warning based on the . . . label change").

Courts similarly have held that claims against generic drug manufacturers for failure to conduct testing of their drug products are pre-empted. *See, e.g.*, *Drager v. PLIVA USA, Inc.*,

741 F.3d 470, 476-77 (4th Cir. 2014) (concluding that a claim that a generic drug manufacturer was negligent in the "testing, inspection, and post-market surveillance" of its drug product was pre-empted because any duty to perform such acts fell within the "general duty to protect consumers from injury based on the negligent marketing and sale of a product," and the manufacturer "whose product is unreasonably dangerous as sold could not satisfy that [general] duty without changing its warnings, changing its formulation, exiting the market, or accepting tort liability"); *Morris*, 713 F.3d at 778 (concluding that a claim that generic drug manufacturers failed to test and inspect their products was pre-empted, in part, because "any 'useful' reporting [of testing results]—at least from the standpoint of those injured—would ostensibly consist of some sort of warning," which the manufacturer could not give).

Courts also have held that claims against generic drug manufacturers for misrepresentation, fraud, and violation of consumer-protection statutes are pre-empted. *See, e.g.*, *In re Darvocet*, 756 F.3d at 935-36 (concluding that fraud, misrepresentation, and consumer-protection claims against generic manufacturers were pre-empted because the claims "all challenge[d] label content," the plaintiffs did "not identify any representations made other than those contained in the FDA-approved labeling," and the manufacturers "could not have corrected any alleged misrepresentation without violating federal law because they were required to conform their labeling to that of the brand-name drugs"); *Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674, 680 (5th Cir. 2014) (concluding that consumer-protection claims against generic manufacturers were pre-empted because the claims were based on allegations that the manufacturers failed to sufficiently warn consumers, and federal law forbade the manufacturers from making any changes to their FDA-approved warnings); *Drager*, 741 F.3d at 479 (concluding that negligent misrepresentation and fraudulent concealment claims against a generic drug manufacturer were

pre-empted because they were premised on the content of the labeling, the manufacturer had "no authority to add or remove information from its materials or to change the formulation of the product to make its representations complete or truthful," and the manufacturer's "only remaining options [were] to leave the market or accept tort liability").

As one final example, courts have held that claims against generic drug manufacturers for breaches of express and implied warranties are pre-empted. *See, e.g.*, *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1288 (10th Cir. 2013) (concluding that an express-warranty claim against a generic drug manufacturer was pre-empted because the plaintiffs did not identify a mechanism through which the manufacturer "could have modified or supplemented the warranties allegedly breached without running afoul of the duty of sameness" and that claims for breach of the implied warranties of merchantability and fitness for intended use were pre-empted because the manufacturer "could not have altered the composition of the [drug] it manufactured without violating federal law"); *Drager*, 741 F.3d at 478-79 (concluding that claims that a generic drug manufacturer had breached an express warranty and the implied warranties of merchantability and fitness for a particular purpose were pre-empted because the manufacturer could not have changed its warnings or drug formulation to comply with the warranties and therefore could avoid liability only by leaving the market).

C. Issues

Defendants contend in their Motion to Dismiss that, under *Mensing* and *Bartlett*, all of the claims against them in each of the Master Complaints are pre-empted and must be dismissed. DE 1582 at 8, 10, 16, 27-42. They assert that, even where Plaintiffs have "creatively pled" their claims by calling them something other than design defect or failure to warn, all of the claims are pre-empted design or labeling defect claims "[a]t their core." *Id.* at 8, 22-26, 28. Plaintiffs maintain

that none of their claims are pre-empted. *See generally* DE 2010-1. The Court now turns to the parties' arguments about specific issues and claims.

1. Misbranding

a. Arguments and Allegations

Plaintiffs assert that their claims against Defendants are not pre-empted because they are "parallel to federal misbranding requirements." *Id.* at 32. They incorporate by reference the arguments that they make about misbranding in their Opposition to Brand-Name Defendants' Rule 12 Partial Motion to Dismiss on Preemption Grounds. *Id.*; *see* DE 1976. In that Opposition, Plaintiffs argue that they have alleged in the Master Complaints that ranitidine products were "misbranded" as that term is defined in 21 U.S.C. § 352(a)(1) and (j). DE 1976 at 20-21, 24. The U.S. Code prohibits the introduction of misbranded drugs into interstate commerce. *Id.* at 11, 21. And state laws prohibit the sale of defectively designed drugs. *Id.* at 21. Therefore, because federal law and state laws prohibit the same action, the sale of drugs that are misbranded and dangerous, there is no conflict between federal and state law and no impossibility in complying with both federal and state law. *Id.* at 17, 21-23.

Defendants reply that no other court has recognized Plaintiffs' misbranding argument and that the argument is actually a stop-selling argument, which the Supreme Court rejected in *Bartlett*. DE 2133 at 15-16. If Plaintiffs' misbranding argument were accepted, any plaintiff in a drug case could avoid pre-emption simply by adding misbranding allegations to the complaint. *Id.* at 12-13. Defendants also incorporate by reference the arguments relating to misbranding in Brand-Name Manufacturer Defendants' Reply Brief in Support of Their Rule 12 Partial Motion to Dismiss Plaintiffs' Three Complaints as Preempted by Federal Law. *Id.* at 15; *see* DE 2134. In that Reply, Brand-Name Manufacturer Defendants add that Plaintiffs have not brought any cause of action

titled "misbranding" in the Master Complaints and that Plaintiffs mention misbranding in only a few causes of action. DE 2134 at 17. Plaintiffs misunderstand the meaning of the federal misbranding statute because a drug product is misbranded only if it fails to contain the FDA-approved labeling. *Id.* at 17-18.

Plaintiffs allege in each Master Complaint that ranitidine products were misbranded because the named defendants "did not disclose NDMA as an ingredient" in the products, "did not disclose the proper directions for storage" of the products, and "did not disclose the proper directions for expiration" of the products. MPIC ¶¶ 421-23; CCCAC ¶¶ 601-03; CTPPCC ¶¶ 338-40. During the Hearing, Plaintiffs clarified that they assert that ranitidine products were misbranded as that term is defined in 21 U.S.C. § 352(a)(1) and (j). DE 2499 at 146.

b. Federal Statutes on Misbranding

The U.S. Code prohibits the "introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded," the "adulteration or misbranding of any . . . drug . . . in interstate commerce," the "receipt in interstate commerce of any . . . drug . . . that is adulterated or misbranded," and the "manufacture within any Territory of any . . . drug . . . that is adulterated or misbranded." 21 U.S.C. § 331(a)-(c), (g). Plaintiffs do not have a private cause of action to enforce this statute. *Id.* § 337(a) (providing that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States"); *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1284 n.10 (11th Cir. 2002) (explaining that "no private right of action exists for a violation of the FDCA"). Section 352 of the U.S. Code contains several sub-sections delineating the circumstances under which a drug "shall be deemed to be misbranded." 21 U.S.C. § 352. As relevant here, a drug is misbranded if "its labeling is false or misleading in any particular" or if "it is dangerous to health when used in the dosage or manner,

or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." *Id.* § 352(a)(1), (j).

c. Misbranding and *PLIVA, Inc. v. Mensing*

When *Mensing* was pending before the Supreme Court, the United States, in an amicus brief on behalf of the FDA, argued that a drug's labeling must be revised to include a warning "as soon as there is reasonable evidence of an association of a serious hazard with a drug."[5] Brief for the United States as Amicus Curiae Supporting Respondents at 6, 12, *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) (Nos. 09-933, 09-1039, 09-1501), 2011 WL 741927 (quotation marks omitted). The FDA maintained that, after such evidence is discovered, a drug that lacks an adequate warning is misbranded. *Id.* at 6, 12-13, 23-24 (citing 21 U.S.C. § 352). The FDA recognized that generic drug manufacturers cannot "unilaterally" change drug labeling so as to prevent their drugs from being misbranded. *Id.* at 12, 15-17 (citing 21 U.S.C. § 355(j)(4)(G) and 21 C.F.R. § 314.94(a)(8)(iii)). But the FDA asserted that generic drug manufacturers have "a duty under federal law" to provide the evidence they discover to the FDA and to propose a labeling change to the FDA, for the FDA to then determine whether the labeling should be changed. *Id.* at 12, 14-15, 20. According to the FDA, when a generic drug manufacturer did not fulfill that duty under federal law, a state claim against the manufacturer for failure to warn would not be pre-empted. *Id.* at 14, 30.

In its opinion in *Mensing*, the Supreme Court recognized the FDA's arguments concerning misbranding and, for the purpose of the opinion, assumed that a duty might exist even under federal

[5] This language is derived from 21 C.F.R. § 201.57, which has been amended to read that "labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug." 21 C.F.R. § 201.57(c)(6)(i); *see* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Rev. 3922-01, 3990 (Jan. 24, 2006) (to be codified at 21 C.F.R. § 201.57). The language cited in the amicus brief, however, continues to apply to "older drugs," meaning drugs for which the FDA approved an NDA before June 30, 2001. *See* 21 C.F.R. §§ 201.56(b)(1)(i), .80(e).

law for a generic drug manufacturer to take action if its drug product is misbranded. *See* 564 U.S. at 616-17 ("Because we ultimately find pre-emption even assuming such a duty existed, we do not resolve the matter."). That, however, did not end the inquiry for the purpose of analyzing federal pre-emption. *See id.* at 617 ("We turn now to the question of pre-emption."). On the issue of impossibility pre-emption, the Court concluded that the consumers' failure-to-warn claims were pre-empted because the generic drug manufacturers could not "independently" change their labeling under federal law and because pre-emption analysis could not depend on what a third party or the federal government might do. *Id.* at 618-21, 623-24 ("The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it."). The Court rejected the FDA's premise in its amicus brief that state-law claims are not pre-empted if a drug is misbranded and the drug's manufacturer fails to act. *Cf. id.* at 613 n.3 (noting that, while a court defers to an agency's interpretation of its own regulations, a court does not defer to an agency's ultimate conclusion about whether state law is pre-empted).

The Eighth Circuit Court of Appeals below had determined that a failure-to-warn claim was not pre-empted both because a generic drug manufacturer can propose a labeling change to the FDA and because the manufacturer has the option of withdrawing an insufficiently labeled product from the market. *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 608-11 (8th Cir. 2009) ("The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product."), *rev'd sub nom. PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011). While the Supreme Court did not explicitly address this stop-selling argument in its *Mensing* opinion, the Court implicitly rejected the argument by holding that the consumers' failure-to-warn claims were

pre-empted. *See Bartlett*, 570 U.S. at 488-90 (discussing *Mensing*'s rejection of the stop-selling argument).

Following the Supreme Court's opinion in *Mensing*, federal courts presented with claims that generic drug manufacturers had distributed misbranded drugs rejected such claims as pre-empted under *Mensing*. *See, e.g., Gardley-Starks v. Pfizer, Inc.*, 917 F. Supp. 2d 597, 607 (N.D. Miss. 2013) (explaining, where a plaintiff asserted that *Mensing* did not apply to a claim that a manufacturer had distributed a misbranded drug, that "no matter how Plaintiff styles her theories of recovery, her claims ultimately relate to the Generic Defendants' alleged failure to warn about the side effect of metoclopramide"); *Moretti v. PLIVA, Inc.*, No. 2:08-CV-00396-JCM, 2012 WL 628502, at *2, 5 (D. Nev. Feb. 27, 2012) (rejecting a plaintiff's argument that *Mensing* did not foreclose liability based on a generic drug manufacturer continuing to distribute a misbranded drug), *aff'd sub nom. Moretti v. Wyeth, Inc.*, 579 F. App'x 563 (9th Cir. 2014); *Moretti v. Mutual Pharm. Co.*, 852 F Supp. 2d 1114, 1118 (D. Minn. 2012) (stating that the court was "not persuaded" by a plaintiff's attempt to differentiate her misbranding claim from the types of claims addressed in *Mensing* and that, "[d]espite the different 'labels' given these claims, the essence of these claims is that . . . Defendants failed to warn of material safety information concerning metoclopramide"), *aff'd*, 518 F. App'x 486 (8th Cir. 2013); *Metz v. Wyeth, LLC*, No. 8:10-CV-2658-T-27AEP, 2011 WL 50 24448, at *4 (M.D. Fla. Oct. 20, 2011) (dismissing plaintiffs' claim that a generic drug was misbranded because the claim fell "directly within the scope of *Mensing* because it [was] based on Actavis' purported failure to provide an adequate label and package insert for metoclopramide").

d. Misbranding and *Mutual Pharmaceutical Co. v. Bartlett*

When *Bartlett* was pending before the Supreme Court, the United States, in an amicus brief on behalf of the FDA, argued that a "pure" design-defect claim under state law that was based on "new and scientifically significant evidence" not previously before the FDA could "parallel" the federal misbranding statute and might not be pre-empted. Brief for the United States as Amicus Curiae Supporting Petitioner at 12, 20-24, *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013) (No. 12-142), 2013 WL 314460 (calling this a "difficult and close" question). The FDA's position was that a "defective-design claim would lie only if based on significant new evidence that triggered a duty under federal law not to market a misbranded drug." *Id.* at 23, 32 (explaining that a state-law duty not to market a misbranded drug "would not conflict with federal law if it appropriately accounted for the FDA's role under the FDCA"). The FDA defined a "pure" design-defect claim as a claim that did "not consider the adequacy of labeling." *Id.* at 12. The FDA opined that the Supreme Court did not need to reach this issue because the New Hampshire law at issue in the case did not recognize "pure" design-defect claims and because the jury below had not been asked to find "new and scientifically significant evidence." *Id.* at 16-17, 20-21, 24.

In its opinion in *Bartlett*, the Supreme Court did "not address state design-defect claims that parallel the federal misbranding statute" because the misbranding statute was "not applicable," as "the jury was not asked to find whether new evidence concerning sulindac that had not been made available to the FDA rendered sulindac so dangerous as to be misbranded." *See* 570 U.S. at 487 n.4 (stating that the "parties and the Government appear to agree that a drug is misbranded under federal law only when liability is based on new and scientifically significant information that was not before the FDA"). The Court also rejected the rationale that a drug manufacturer could comply with conflicting state and federal law by stopping selling an unsafe drug. *Id.* at 475,

488 ("Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability."). The Court explained that it had rebuffed this stop-selling rationale in *Mensing*. *Id.* at 489-90 ("In concluding that it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same, the Court was undeterred by the prospect that PLIVA could have complied with both state and federal requirements by simply leaving the market." (citation and quotation marks omitted)).

Following the Supreme Court's opinion in *Bartlett*, some federal courts have been presented with misbranding claims against drug manufacturers and have rejected the claims either because the law of the state at issue did not recognize a "pure" design-defect claim or because the misbranding claim was not based on new and scientifically significant evidence that was not before the FDA. *See Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 299 n.3 (6th Cir. 2015) (concluding that a plaintiff could not "stave off preemption" by mentioning misbranding where she had not cited any new and scientifically significant evidence not before the FDA); *In re Darvocet*, 756 F.3d at 929-30 (explaining that the plaintiffs failed to identify a state claim that had elements identical to a federal misbranding claim and failed to point to new and scientifically significant evidence that the generic drug manufacturers possessed that was not before the FDA); *Schrock*, 727 F.3d at 1290 (stating that the plaintiffs had not advanced a misbranding claim that was based on new and scientifically significant information not before the FDA); *In re Yasmin and Yaz (Drospirenone) Mktg., Sales Pracs. & Prods. Liab. Litig.*, No. 3:09-md-02100-DRH-PMF, 2015 WL 7272766, at *4 (S.D. Ill. Nov. 18, 2015) (determining that the plaintiff could not "assert a 'pure' design defect claim under Illinois law"). However, none of these cases have ruled on the issue that the Supreme Court declined to address in *Bartlett*: whether a claim based on an allegation

that a drug was misbranded escapes pre-emption if the claim is brought under the law of a state that recognizes a "pure" design-defect claim and is based on new and scientifically significant evidence not before the FDA. *See, e.g.*, *In re Darvocet*, 756 F.3d at 929 (declining to resolve the "possibly thorny issue" of whether a misbranding claim creates an exception to impossibility pre-emption because the plaintiffs "failed to plead such a claim"); *see also Bartlett*, 570 U.S. at 487 n.4.

e. Analysis and Conclusion

No court has adopted Plaintiffs' theory that impossibility pre-emption can be avoided by showing that a drug is misbranded. *Mensing* and *Bartlett* dictate that Plaintiffs' claims are pre-empted if they are based on alleged product defects that Defendants could not independently change while remaining in compliance with federal law, even if those defects rendered the products misbranded. *Mensing* and *Bartlett* further instruct that the ability to comply with both federal and state law by withdrawing misbranded ranitidine products from the market does not defeat pre-emption. A claim based on an allegation that a generic drug's labeling renders the drug misbranded is a pre-empted claim because the drug's manufacturer cannot independently and lawfully change FDA-approved labeling.[6] *See Mensing*, 564 U.S. at 618-21. Likewise, a claim based on an allegation that a generic drug's formulation renders the drug misbranded is a pre-empted claim because the drug's manufacturer cannot independently and lawfully change a drug formulation that the FDA has approved. *See Bartlett*, 570 U.S. at 483-84 (citing 21 U.S.C. § 355(j)).

[6] The Court takes no position as to whether state-law claims would be pre-empted where a drug product was misbranded because it did not contain the FDA-approved labeling. Plaintiffs have not alleged or argued that any ranitidine products did not contain the FDA-approved labeling. A circuit split exists on the issue of whether a claim based on failure to use FDA-approved labeling is pre-empted. *See Wagner v. Teva Pharms. USA, Inc.*, 840 F.3d 355, 359-60 & n.1 (7th Cir. 2016) (noting this split of authority between the Fifth and Sixth Circuits and declining to take a position, citing *Morris*, 713 F.3d 774 and *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013)).

The fact that federal law imposes criminal liability on a drug manufacturer that introduces a misbranded drug into interstate commerce is of no matter. *See* 21 U.S.C. §§ 331(a)-(c), (g), 333 (providing penalties for misbranding crimes). It does not follow that, because a drug manufacturer that introduces a misbranded drug into interstate commerce is subject to criminal liability, a civil remedy must also be available. There is no private cause of action to enforce the federal misbranding statutes. *See id*. § 337(a); *Ellis*, 311 F.3d at 1284 n.10.

A finding that Plaintiffs can avoid pre-emption by alleging that defects in ranitidine products made the products misbranded under 21 U.S.C. § 352 would render the vast body of pre-emption caselaw in the drug context, including binding Supreme Court decisions, meaningless. If Plaintiffs' position were accepted, a plaintiff could avoid pre-emption simply by asserting, for example, that a drug's labeling was "false or misleading in any particular" or that the drug was "dangerous to health when used" as prescribed. *See* 21 U.S.C. § 352(a)(1), (j). The Court cannot adopt a position that would render pre-emption caselaw meaningless. *Cf. Bartlett*, 570 U.S. at 488-90 (rejecting the stop-selling rationale because it was "incompatible with our pre-emption jurisprudence," would mean that the vast majority or all "of the cases in which the Court has found impossibility pre-emption, were wrongly decided," and would make impossibility pre-emption "all but meaningless" (quotation marks omitted)); *Mensing*, 564 U.S. 620-21 (rejecting the proposition that pre-emption analysis could be dependent on what a third party or the federal government might do because such a position would "render conflict pre-emption largely meaningless").

Thus, Plaintiffs' claims based on alleged defects in ranitidine products, product labeling, or other communications that Generic Manufacturer Defendants could not independently change while remaining in compliance with federal law are pre-empted. This includes, but is not limited to, claims based on allegations that ranitidine products were defectively designed because they

break down into NDMA and claims based on failure to warn consumers that the products contained NDMA or could break down into NDMA when ingested. *See, e.g.*, MPIC ¶¶ 461, 478, 508, 522, 551, 566, 579, 593, 617, 630; *see also* 21 U.S.C. § 355(j)(2)(A) (requiring generic drug products to have the same active ingredient(s), route of administration, dosage form, strength, therapeutic effect, and labeling as the listed drug and be bioequivalent to the listed drug). The Court finds it unnecessary to identify every allegation in the 7,236 numbered paragraphs in the Master Complaints involving an action that Generic Manufacturer Defendants could not independently and lawfully take. The Court places confidence in the ability of Plaintiffs' counsel to, in good faith, identify these allegations and to omit them from claims against Generic Manufacturer Defendants upon repleading the Master Complaints.

Plaintiffs do not contend that Repackager Defendants could lawfully make product or labeling changes that Generic Manufacturer Defendants could not lawfully make. The same pre-empted claims against Generic Manufacturer Defendants are likewise pre-empted as against Repackager Defendants.

Finally, Brand-Name Manufacturer Defendants assert in their Reply Brief in Support of Their Rule 12 Partial Motion to Dismiss Plaintiffs' Three Complaints as Preempted by Federal Law (which Defendants incorporate by reference) and argued during the Hearing that a drug product is misbranded only if it fails to contain the FDA-approved labeling. DE 2134 at 17-18; DE 2499 at 126, 130; *see* DE 2133 at 15. Defendants and Brand-Name Manufacturer Defendants have not pointed to any authority providing that definition of misbranding. The statute delineating when a drug is misbranded does not contain the definition that Defendants and Brand-Name Manufacturer Defendants propose. *See* 21 U.S.C. § 352. Nor is it apparent that the FDA defines misbranding in such a way, as the FDA maintained in its amicus brief in *Bartlett* that a drug may

be misbranded if new and scientifically significant information concerning the drug's safety comes to light. *See* Brief for the United States as Amicus Curiae Supporting Petitioner at 21-22, *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013) (No. 12-142), 2013 WL 314460 (citing 21 U.S.C. § 352(j)).

The Court does not resolve this issue. For the purpose of this Order, the Court assumes, without finding, that Plaintiffs have adequately alleged that ranitidine products were misbranded. The Court nevertheless concludes that Plaintiffs' allegations of misbranding have no bearing on the holdings of *Mensing* and *Bartlett*.

Plaintiffs' claims based on alleged product and labeling defects that Defendants could not independently change while remaining in compliance with federal law are dismissed with prejudice as pre-empted. Because all of Plaintiffs' counts against Defendants in the Master Complaints incorporate such allegations, all counts against Defendants are dismissed.

2. Expiration Dates and Testing

a. Arguments and Allegations

Plaintiffs contend that there was at least one piece of information on the packaging of ranitidine products that Defendants could change without FDA pre-approval, that is, the expirations dates for the products.[7] DE 2010-1 at 13-18. Under federal law, an expiration date for a generic product need not be the same as the expiration date for the listed brand-name drug. *Id.* at 12, 16-18, 20, 26-27. Defendants could and should have shortened the expiration dates for ranitidine products because the products did not remain "stable" through the expiration dates on

[7] Plaintiffs cite to evidence outside of the Master Complaints to support this point. DE 2010-1 at 27-28. The Court disregards this evidence for the purpose of ruling on the Motion to Dismiss. *See Bickley v. Caremark RX, Inc.*, 461 F.3d 1325, 1329 n.7 (11th Cir. 2006) (stating that a court considering a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) "generally is limited to reviewing what is within the four corners of the complaint," but may consider documents referred to in the complaint if those documents are central to the plaintiff's claim); *see also* Fed. R. Civ. P. 12(d) (requiring a motion to dismiss under Rule 12(b)(6) to be treated as a motion for summary judgment under Rule 56 if "matters outside the pleadings are presented to and not excluded by the court").

the packaging and developed higher levels of NDMA as time passed. *Id.* at 25-26. Defendants could have known that expiration dates for ranitidine products should have been shorter had they conducted adequate testing of their products. *Id.* at 11-13, 21, 26. Thus, Plaintiffs can pursue state-law claims that are based on failure to warn that ranitidine products had expired and failure to test the products to learn of their expiration. *Id.* at 9, 20, 22-23.

Defendants, citing to some of the same cases that the Court cites in Section VII.B.4. of this Order, argue that federal courts have ruled that claims against generic drug manufacturers for failure to conduct testing of their drug products are pre-empted. DE 1582 at 25-26, 37; DE 2133 at 7, 17-19; *see, e.g.*, *Drager*, 741 F.3d at 476-77; *Morris*, 713 F.3d at 778. Plaintiffs' allegations and arguments about shortening expiration dates are "fundamentally inconsistent" with other allegations in the Master Complaints and are "irrelevant" because "Plaintiffs' claims are grounded in the theory that the labeling was deficient because it did not warn of the risk of cancer or the presence of NDMA, that there is *no* safe level of NDMA, and that *all* ranitidine medications contain elevated levels of NDMA." DE 2133 at 7, 19-21.

Plaintiffs allege in the MPIC that stability testing of a drug determines the appropriate expiration date for the drug and that continued stability testing verifies that the expiration date remains appropriate. MPIC ¶¶ 371, 373. Stability testing that the FDA conducted "revealed NDMA levels were higher as [ranitidine] products approached their expiration dates" and "raised concerns that NDMA levels in some ranitidine-containing products stored at room temperature can increase with time to unacceptable levels." *Id.* ¶¶ 302, 407. This testing "eroded the [FDA's] confidence that any ranitidine-containing product could remain stable through its labeled expiration date," and therefore the FDA "withdrew the products from the market." *Id.* ¶ 302. The named defendants "did not conduct adequate stability testing of their product to ascertain . . .

expiration" and did not communicate appropriate expiration dates. *Id.* ¶¶ 467, 481(e), (j), 552. The named defendants could have provided appropriate expiration dates and had a duty to provide appropriate expiration dates. *Id.* ¶¶ 457, 486. The named defendants would have known of the danger that ranitidine products posed had they properly tested the products. *Id.* ¶¶ 460, 507. Alternatively, Plaintiffs allege that the named defendants did test ranitidine products and did know of the danger that the products posed, but nevertheless continued to market the products. *Id.* ¶¶ 450-51, 454, 460, 507, 556(t). Plaintiffs make similar allegations in the CCCAC and the CTPPCC.

b. Federal Regulations on Expiration Dates and Testing

"There shall be a written testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates." 21 C.F.R. § 211.166(a). "To assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, it shall bear an expiration date determined by appropriate stability testing . . . ." *Id.* § 211.137(a). "Expiration dates shall be related to any storage conditions stated on the labeling . . . ." *Id.* § 211.137(b). The expiration date on the proposed labeling included in an ANDA for a generic drug need not be the same as the expiration date for the listed drug. *Id.* § 314.94(a)(8)(iv).

According to FDA guidance that the parties cite, a "[r]eduction of an expiration dating period to provide increased assurance of the identity, strength, quality, purity, or potency of the drug product" is a moderate change that may be made through the CBE process. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Guidance for Industry: Changes to an Approved NDA or ANDA (April 2004),

https://www.fda.gov/media/71846/download.[8] None of the parties have pointed to any case where a claim based on failure to shorten the expiration date for a drug has been presented to a court.

c. Analysis and Conclusion

The Supreme Court explained in *Wyeth v. Levine* that a failure-to-warn claim is not pre-empted if a drug manufacturer has the ability to change drug labeling through the CBE process without waiting for FDA approval, unless there is evidence that the FDA would reject the change. 555 U.S. at 568-73. Therefore, if it is accepted that the expiration date for a generic drug need not be the same as for the listed brand-name drug, and if it is accepted that a generic drug manufacturer can shorten the expiration dates on its drug products through the CBE process without FDA pre-approval, then Plaintiffs might be able to bring claims based on the expiration dates for ranitidine products that are not pre-empted.

However, the Master Complaints do not state claims based on expiration dates and testing upon which relief can be granted. First, Plaintiffs have not pled any counts in the Master Complaints that are devoted to expiration dates or to testing. Plaintiffs instead incorporate their allegations about expiration dates and testing, along with all of their other allegations, into every one of their counts.

Second, Plaintiffs have not identified in the Master Complaints the state-law duty or duties for each of the 52 jurisdictions that they maintain Defendants did not fulfill when they did not shorten expiration dates for ranitidine products. By the Court's understanding, Plaintiffs raise their allegations concerning expiration dates under the duty to warn, the duty to test, or both. *See, e.g.*, MPIC ¶¶ 467, 481(j), 552. Some states recognize negligent testing as a tort that is independent of

[8] The parties agree that the Court may take judicial notice of this FDA guidance manual and consider it at the motion-to-dismiss stage. DE 2499 at 38-39; *see Gustavsen v. Alcon Lab'ys, Inc.*, 272 F. Supp. 3d 241, 252-53 (D. Mass. 2017) (explaining that it is proper for courts to take judicial notice of public documents such as material appearing on government websites, and considering material on the FDA's website on a motion to dismiss).

design-defect, manufacturing-defect, and failure-to-warn claims, while other states do not. *Compare Atkinson v. Luitpold Pharms., Inc.*, 448 F. Supp. 3d 441, 453-54 (E.D. Pa. 2020) (citing Texas caselaw for the proposition that "in Texas there is an independent cause of action based on negligent failure to test"), *with Kociemba v. G.D. Searle & Co.*, 707 F. Supp. 1517, 1527 (D. Minn. 1989) (concluding that, under Minnesota law, a manufacturer's duty to inspect and test its products is subsumed within the duties to safely design, safely manufacture, and adequately warn). Plaintiffs have not identified in the Master Complaints which duties under which states' laws apply to Generic Manufacturer Defendants, Repackager Defendants, or both.

Third, Plaintiffs have not brought their state-law claims in the MPIC and the CTPPCC in separate counts by jurisdiction. Instead, each count in the MPIC and the CTPPCC that raises a state-law claim is brought under the laws of many or all of the 52 jurisdictions—50 states, Puerto Rico, and the District of Columbia—at issue in this MDL. To provide needed clarity as to their allegations, upon repleading Plaintiffs should bring all claims arising under separate states' laws in separate counts in each of the Master Complaints. *See* Fed. R. Civ. P. 10(b) ("If doing so would promote clarity, each claim founded on a separate transaction or occurrence . . . must be stated in a separate count or defense.").

As Defendants point out, Plaintiffs' allegations that expiration dates for ranitidine products should have been shortened because the products became dangerous over time are inconsistent with their allegations that the products were dangerous upon being manufactured. *See, e.g.*, MPIC ¶¶ 345, 476 (alleging that ranitidine products were "inherently dangerous" "[a]t all relevant times" and that testing has revealed that the products contain "elevated levels of NDMA" after two weeks). Pleading in the alternative is permissible. Fed. R. Civ. P. 8(d)(2) ("A party may set out 2 or more statements of a claim or defense alternatively or hypothetically, either in a single count

or defense or in separate ones."); *Adinolfe v. United Techs. Corp.*, 768 F.3d 1161, 1175 (11th Cir. 2014) ("It is a well-settled rule of federal procedure that plaintiffs may assert alternative and contradictory theories of liability."). However, a party may not plead internally inconsistent facts within a count. *See Campos v. Immigr. & Naturalization Serv.*, 32 F. Supp. 2d 1337, 1343 (S.D. Fla. 1998) (explaining that a court need not accept internally inconsistent factual allegations in a complaint); *see also Joseph v. Chronister*, No. 8:16-cv-274-T-35CPT, 2019 WL 8014507, at *9 (M.D. Fla. Jan. 3, 2019) (determining that a plaintiff permissibly pled in the alternative where his inconsistent factual allegations were pled in separate counts); *McMahon v. City of Riviera Beach*, No. 08-80499-CIV, 2008 WL 4108051, at *3 (S.D. Fla. Aug. 28, 2008) (concluding that a plaintiff's incorporation of inconsistent factual allegations within counts was "fatal" to the counts). Plaintiffs' incorporation of inconsistent factual allegations into their counts is improper.

Finally, the Court addresses an issue raised during the Hearing. Plaintiffs asserted that "preemption applies only to the extent of the difference between state and Federal responsibilities." DE 2499 at 26-27. Plaintiffs explained that, if "a state cause of action creates duties A, B, and C, and Federal law makes it impossible to comply with duty C," then a plaintiff "can still plead and prove her case based on either . . . a breach of duty A, or a breach of duty B," and there "is only preemption to the extent of the difference." *Id.* at 27. To support their assertion, Plaintiffs pointed to statements in Supreme Court opinions such as *Reigel v. Medtronic, Inc.*, *Bates v. Dow Agrosciences LLC*, and *Medtronic, Inc v. Lohr*. *See Reigel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) ("State requirements are pre-empted under [21 U.S.C. § 360k(a) of the Medical Device Amendments of 1976] only to the extent that they are different from or in addition to the requirements imposed by federal law." (quotation marks omitted)); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 453 (2005) (remanding for a lower court to determine whether a provision of

the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136v(b), expressly pre-empted Texas fraud and failure-to-warn claims and stating that, "were the Court of Appeals to determine that the element of falsity in Texas' common-law definition of fraud imposed a broader obligation than FIFRA's requirement that labels not contain 'false or misleading statements,' that state-law cause of action would be pre-empted by § 136v(b) to the extent of that difference"); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996) (explaining that "additional elements" of a state-law cause of action that "make the state requirements narrower, not broader, than the federal requirement" do not necessarily render the cause of action different from federal law and expressly pre-empted under 21 U.S.C. § 360k(a) of the Medical Device Amendments of 1976).

Reigel, *Bates*, and *Lohr* did not address impossibility pre-emption. In each case, the Supreme Court examined a statutory provision that expressly pre-empted state law that was "different from" federal law, and therefore state law was pre-empted only to the extent of its difference from federal law. *See* 7 U.S.C. § 136v(b) ("Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter."); 21 U.S.C. § 360k(a) (providing that "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement . . . which is different from, or in addition to, any requirement applicable under this chapter to the device"); *see also English*, 496 U.S. at 78 (explaining that express pre-emption exists when Congress "define[s] explicitly the extent to which its enactments pre-empt state law").

During the Hearing, the parties agreed that impossibility pre-emption exists when state law imposes a duty or obligation on a party to do something, but federal law prevents the party from doing it. DE 2499 at 38. "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Mensing*, 564 U.S. at 618, 620

(finding impossibility where it "was not lawful under federal law for the Manufacturers to do what state law required of them"); *see also English*, 496 U.S. at 79 (explaining that impossibility pre-emption exists when "it is impossible for a private party to comply with both state and federal requirements"). If a defendant cannot, independently and while remaining in compliance with federal law, do what needs to be done to avoid liability under a state cause of action, the cause of action is pre-empted. *See Bartlett*, 570 U.S. at 486-87 (concluding that a state-law design-defect claim was pre-empted because federal law prohibited the generic drug manufacturer "from taking the remedial action required to avoid liability" under state law). Upon any repleading, Plaintiffs should consider, as to each cause of action, the elements under each state's law and what state law would require of Defendants to avoid liability.

For the reasons given herein, Plaintiffs' claims based on allegations that Defendants should have shortened the expiration dates on ranitidine products or should have conducted testing of the products are dismissed without prejudice and with leave to amend.

3. Storage and Transportation Conditions

a. Arguments and Allegations

Defendants contend that any claims that they should have placed different storage and transportation information on ranitidine product labeling or "implemented" different storage and transportation conditions for the products are pre-empted. DE 1582 at 29, 36. This is so because Defendants could not independently and lawfully change FDA-approved labeling, including any storage and transportation information on labeling, and because they were bound to comply with the storage and transportation instructions on labeling. *Id.* at 29, 36.

Plaintiffs respond that they "do not accept" Defendants' assertion that they could not lawfully change storage and transportation information listed on the labeling for ranitidine

products. DE 2010-1 at 39. At this stage of the litigation, the Court must accept as true Plaintiffs' allegations that Defendants could have changed storage and transportation information on the labeling and could have learned of the appropriate storage and transportation information through stability testing. *Id.* at 23, 39.

Plaintiffs allege in the MPIC that adequate stability testing of ranitidine products would have revealed the appropriate storage and transportation conditions for the products, including the appropriate conditions relating to temperature and exposure to light. MPIC ¶¶ 371, 407, 481(j), 556(g). The named defendants failed to conduct adequate stability testing of ranitidine products. *Id.* ¶¶ 481(j), 523(e), 556(g). Ranitidine products contained "false and misleading" storage and transportation information on the labeling, and the named defendants did not attempt to correct that information or to add the proper storage and transportation information. *Id.* ¶¶ 383, 385, 388, 414, 422, 481(g). The named defendants had a duty to communicate appropriate storage and transportation information for ranitidine products, and they breached that duty. *Id.* ¶¶ 414, 457. In addition, the Manufacturer Defendants failed to "implement appropriate handling instructions and storage conditions" for ranitidine products. *Id.* ¶¶ 496(e), 536(e). Plaintiffs make similar allegations in the CCCAC and the CTPPCC.

b. Relevant Federal Law

As already explained, an ANDA must contain information showing that the generic drug has the same labeling as the labeling approved for the listed drug. 21 U.S.C. § 355(j)(2)(A)(v), (4)(G); *see also* 21 C.F.R. § 314.94(a)(8)(iv). According to FDA guidance, a "[c]hange in the labeled storage conditions, unless exempted by regulation or guidance" is a major change that requires the submission of a Prior Approval Supplement and FDA approval. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and

Research, Guidance for Industry: Changes to an Approved NDA or ANDA (April 2004), https://www.fda.gov/media/71846/download. Claims that are based on alleged labeling defects that a defendant could not independently change while remaining in compliance with federal law are pre-empted. *Mensing*, 564 U.S. at 618-21, 623-24.

c. Analysis and Conclusion

The Court is not aware of any authority standing for the proposition that storage and transportation information on FDA-approved labeling for a generic drug is treated differently than other labeling information that must match what the FDA has approved for the listed brand-name drug. For example, the Court knows of no authority providing that the FDA may approve proposed labeling in an ANDA if it adds, omits, or contains different storage and transportation information from the FDA-approved brand-name labeling. The Court similarly is not aware of any authority providing that generic drug manufacturers or repackagers can change storage and transportation information on labeling without FDA pre-approval while remaining in compliance with federal law. In addition, Plaintiffs acknowledged during the Hearing that "changing the storage and transport conditions to the extent that it could impact the identity, quality, and purity profile of the drug and pose risk to the ultimate consumer would constitute a major change." DE 2499 at 46.

Because claims based on labeling defects that a defendant cannot independently change while remaining in compliance with federal law are pre-empted, Plaintiffs' claims based on allegations that Defendants should have placed different or additional storage and transportation information on their ranitidine products' labeling are dismissed with prejudice as pre-empted. In addition, Plaintiffs claims based on allegations that Defendants should have conducted better testing of ranitidine products to enable them to provide the appropriate storage and transportation information on labeling are dismissed with prejudice as pre-empted. *See, e.g.*, *Morris*, 713 F.3d at

778 (concluding that a claim that generic drug manufacturers failed to test and inspect their products was pre-empted because the manufacturers could not have used the testing results to independently make a change to the products); *Metz v. Wyeth, LLC*, 872 F. Supp. 2d 1335, 1342 (M.D. Fla. 2012) (concluding that a claim that a generic drug manufacturer failed to conduct adequate testing was pre-empted under *Mensing* because, even if the manufacturer had conducted adequate testing, it could not have independently furnished the testing results to consumers or the medical community).

During the Hearing, Plaintiffs clarified that, by pleading that Defendants failed to "implement appropriate handling instructions and storage conditions" for ranitidine products, Plaintiffs meant that "Defendants kept [r]anitidine products under the wrong conditions within their own facilities." DE 2499 at 46; *see also* MPIC ¶¶ 496(e), 536(e). Plaintiffs asserted that they have plausibly pled that Defendants, as well as other named defendants, did not adhere to the proper storage and transportation conditions for ranitidine products. DE 2499 at 46, 51, 78, 114-15. Plaintiffs pointed to their allegations in paragraphs 407, 409, and 457 of the MPIC. *Id.* at 114-15. They acknowledged that they do not know what actions any named defendant took that resulted in ranitidine products being kept under the incorrect conditions, but Plaintiffs asserted that they should be permitted to learn this information through discovery. *Id.* at 50-51, 77, 114-15, 119

The Court declines to determine at this juncture whether a state-law claim for failure to store ranitidine products under the correct conditions is pre-empted. This is because, to the extent that it is Plaintiffs' intent to hold Defendants liable for storing ranitidine products under the wrong conditions, such a theory is not pled. Paragraphs 407, 409, and 457 of the MPIC do not allege that Defendants stored ranitidine products under the wrong conditions. *See* MPIC ¶¶ 407, 409, 457. The paragraphs certainly do not plead specific facts such as the identification of which named

defendants kept ranitidine products under the wrong conditions or of how the conditions under which any products were kept differed from what Plaintiffs maintain were the proper storage conditions. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007) (requiring a complaint to provide sufficient factual allegations to "state a claim to relief that is plausible on its face" and to "raise a right to relief above the speculative level"); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (stating that a complaint must offer more than labels, conclusory statements, and naked assertions devoid of factual enhancement to plead a claim upon which relief can be granted).

To the extent that Plaintiffs, upon repleading, maintain that Defendants stored ranitidine products as provided on the labeling but still stored them under the wrong conditions, Plaintiffs should be prepared to explain how Defendants can be found liable for storing the products in accordance with the labeling. Plaintiffs should be prepared to provide the factual and legal basis for a proposition that, if FDA-approved labeling permits a party to store a drug under certain conditions, a state may nonetheless impose liability for storing the drug under those conditions. To the extent that Plaintiffs maintain that individual Defendants stored ranitidine products under different conditions than those listed on the labeling, Plaintiffs should be prepared to explain how that is an issue for an MDL (which is designed to adjudicate common questions of fact and law) and not an individualized and fact-specific issue. *See* Order Granting Retailer and Pharmacy Defendants' Rule 12 Motion to Dismiss on the Ground of Preemption, Granting Distributor Defendants' Rule 12 Motion to Dismiss on the Ground of Preemption, Denying as Moot Retailer and Pharmacy Defendants' Rule 12 Motion to Dismiss on State Law Grounds, and Denying as Moot Distributor Defendants' Rule 12 Motion to Dismiss on Various Group-Specific Grounds.

4. Warning the FDA

a. Arguments

Plaintiffs contend that the laws of "a wide swath of states" require drug manufacturers to warn the FDA of potential hazards. DE 2010-1 at 9, 20, 28-29. In those states, the failure of a drug manufacturer to do so is a breach of a duty owed to drug consumers. *Id.* at 31, 36-37. And federal law allows or even requires drug manufacturers to warn the FDA of potential hazards. *Id.* at 9, 20. Consequently, warning the FDA is not impossible, and state claims based on Defendants' failure to warn the FDA of hazards are not pre-empted. *Id.* at 30. Defendants reply that the Supreme Court in *Mensing* rejected the consumers' theory based on failure to ask the FDA for help, and therefore the Court ruled that claims based on failure to warn the FDA are pre-empted. DE 2133 at 6, 13-15.

b. Caselaw on Warning the FDA

In *Mensing*, the consumers brought state-law claims for failure to provide adequate warnings on drugs' labeling. 564 U.S. at 610. The consumers denied that their claims were based on the generic drug manufacturers' failure to ask the FDA for assistance in changing drug labeling. *Id.* at 619. The Supreme Court, applying Minnesota and Louisiana law, explained that "[s]tate law demanded a safer label; it did not instruct the [generic drug manufacturers] to communicate with the FDA about the possibility of a safer label" and concluded that "asking for the FDA's help" was "not a matter of state-law concern." *Id.* at 619, 624.

In *Buckman Co. v. Plaintiffs' Legal Committee*, the Supreme Court ruled that the plaintiffs' claims that a company had made fraudulent representations to the FDA during the approval process for a medical device were pre-empted because the federal regulatory scheme tasks the FDA with detecting, deterring, and punishing fraud on the FDA. 531 U.S. 341, 343, 348 (2001) (holding that

"the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law"). The Court reasoned that permitting state law to also police fraud on the FDA would create "conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350, 353 (explaining that "this sort of [state] litigation would exert an extraneous pull on the scheme established by Congress"); *see also English*, 496 U.S. at 79 (explaining that state law is pre-empted when it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" (quotation marks omitted)).

The Eleventh Circuit Court of Appeals relied on *Buckman* in *Tsavaris v. Pfizer, Inc.*, where a plaintiff sought to bring a claim that a drug manufacturer had breached its duty under federal law to notify the FDA of scientific studies connecting the use of a drug to the development of cancer. 717 F. App'x 874, 876 (11th Cir. 2017). The court determined that such a claim was pre-empted because the plaintiff was not attempting to enforce a duty of care owed to her, but rather to enforce a federal reporting duty owed to the FDA. *Id.* at 877. "Preemption occurs when the federal government has exclusive power to punish an individual or entity for a violation of a federal statute or regulation." *Id.* (citing *Buckman*, 531 U.S. at 348).

c. Analysis and Conclusion

According to Plaintiffs, *Buckman* and *Tsavaris* are distinguishable because Plaintiffs are asserting a duty owed to consumers under state law, not a duty owed to the FDA or fraud on the FDA; and *Mensing* did not address this claim because the consumers brought their claims for failure to adequately label, not for failure to warn the FDA, and the states at issue did not recognize claims for failure to warn the FDA. DE 2010-1 at 30, 34-37. The Court declines to determine at this juncture whether a state-law claim for failure to warn the FDA, where the duty at issue is one

that is owed to consumers, is pre-empted. This is because Plaintiffs have not pled any claims for failure to warn the FDA. During the Hearing, when asked where in the Master Complaints they raised claims of failure to warn the FDA, Plaintiffs pointed generally to their failure-to-warn counts, such as Counts I and IV of the MPIC. DE 2499 at 60-61. But those counts do not contain allegations that Defendants should have warned the FDA. Plaintiffs' failure-to-warn counts contain allegations relating only to warnings on the labeling of ranitidine products and warnings to consumers through other mediums. *See, e.g.*, MPIC ¶¶ 454-71, 501-16. Should Plaintiffs choose to plead claims for failure to warn the FDA upon repleading, they should do so consistent with the pleading issues that the Court addresses in Section VII.C.2.c. of this Order.

5. Manufacturing Defect

a. Arguments and Allegations

Defendants argue that Plaintiffs' manufacturing-defect counts must be dismissed because "this is not a case where particular batches of ranitidine made by certain defendants may have contained NDMA due to some error in the manufacturing process that caused those batches to depart from the intended design." DE 1582 at 9, 32. Plaintiffs' allegations are that "an inherent flaw in the design of the ranitidine molecule itself created conditions ripe for NDMA formation in *every* unit of ranitidine made by *every* branded manufacturer and *every* generic manufacturer." *Id.* at 9-10, 32. Plaintiffs' manufacturing-defect claims are actually design-defect claims and are pre-empted. *Id.* at 30-32. Further, any manufacturing changes that Plaintiffs propose in the Master Complaints are "major changes" that Defendants could not have made independently without FDA pre-approval, such that claims based on those changes are pre-empted. *Id.* at 33-35.

Plaintiffs do not dispute that a claim would be pre-empted if it were based on an assertion that the drug manufacturer should have made a manufacturing change that could not be made

independently without FDA pre-approval. Plaintiffs maintain, however, that a drug can be both defectively designed and defectively manufactured and that the manufacturing-defect claims they have pled cannot be deemed pre-empted without discovery and further factual development. DE 2010-1 at 37-38.

Plaintiffs allege in the MPIC that ranitidine products "were expected to and did reach Plaintiffs without a substantial change in their anticipated or expected design" "[a]t all relevant times." MPIC ¶¶ 462, 477, 492. Plaintiffs, in fact, include this allegation within their count in the MPIC for strict liability manufacturing defect. *Id.* ¶ 492. Plaintiffs further allege that ranitidine products were "defective with respect to their manufacture" due to failures to follow Current Good Manufacturing Practices and to "implement procedures that would reduce or eliminate NDMA levels in ranitidine-containing products."[9] *Id.* ¶¶ 494, 496(a), (d), 536(a), (c). Plaintiffs make similar allegations in the CCCAC. The CTPPCC does not contain a manufacturing-defect count. Repackager Defendants are not named under the manufacturing-defect counts in the MPIC but are named under the manufacturing-defect counts in the CCCAC.

b. Law on Manufacturing Defects

A product contains a manufacturing defect "when the product departs from its intended design." Restatement (Third) of Torts: Products Liability § 2(a) (Am. L. Inst. 1998). As to the production of drug products, a "major manufacturing change" is a manufacturing change that has "substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of a drug." 21 U.S.C. § 356a(c)(2); *see also* 21 C.F.R. § 314.70(b)(1). This includes a change "in the qualitative or quantitative formulation" of the drug product or a change in the "manufacture of the drug substance that may affect the

[9] The manufacturing-defect counts also contain allegations about testing, expiration dates, and storage conditions. Those issues are separately addressed above.

impurity profile and/or the physical, chemical, or biological properties of the drug substance." 21 U.S.C. § 356a(c)(2)(A); 21 C.F.R. § 314.70(b)(2)(i), (iv). A drug product that is made with a major manufacturing change may be distributed only upon the submission of a Prior Approval Supplement to the FDA and FDA approval. 21 U.S.C. § 356a(c)(1); *see also* 21 C.F.R. § 314.70(b).

c. Analysis and Conclusion

Plaintiffs have not pled a plausible manufacturing-defect claim. *See Twombly*, 550 U.S. at 555, 570 (requiring a complaint to provide sufficient factual allegations to "state a claim to relief that is plausible on its face" and to "raise a right to relief above the speculative level"). Not only do Plaintiffs allege within a manufacturing-defect count itself that ranitidine products reached consumers without a substantial change to their design, but Plaintiffs also fail to plead any specific facts such as the identification of how any particular batch of ranitidine products departed from their intended design or of any particular manufacturing processes or procedures that should have been but were not followed. *See Iqbal*, 556 U.S. at 678 (stating that a complaint must offer more than labels, conclusory statements, and naked assertions devoid of factual enhancement to plead a claim upon which relief can be granted). The Court is unprepared to conclude, as Defendants maintain, that Plaintiffs are wholly unable to plausibly plead a manufacturing-defect claim. *See* DE 1582 at 30. And in this posture of the pleadings, the Court is unable to evaluate Defendants' contention that the manufacturing-defect claims are pre-empted. Plaintiffs' manufacturing-defect counts against Generic Manufacturer Defendants are dismissed without prejudice and with leave to amend.

Plaintiffs do not separately address the manufacturing-defect counts against Repackager Defendants in the CCCAC. Repackager Defendants are not alleged to have manufactured

ranitidine products.[10] *See* CCCAC ¶ 416 (defining Repackager Defendants as entities that repackaged ranitidine products into different containers and changed "the content on an original manufacturer's label to note the drug [was] distributed or sold under the relabeler's own name," "without manipulating, changing, or affecting the composition or formulation of the drug"). To the extent that Plaintiffs seek to hold Repackager Defendants liable for any manufacturing defects under an absolute-liability theory, absolute liability is addressed briefly in Section VII.C.7. of this Order and more expansively in the Order Granting Retailer and Pharmacy Defendants' Rule 12 Motion to Dismiss on the Ground of Preemption, Granting Distributor Defendants' Rule 12 Motion to Dismiss on the Ground of Preemption, Denying as Moot Retailer and Pharmacy Defendants' Rule 12 Motion to Dismiss on State Law Grounds, and Denying as Moot Distributor Defendants' Rule 12 Motion to Dismiss on Various Group-Specific Grounds. For the reasons given in that Order, Plaintiffs' manufacturing-defect counts against Repackager Defendants are dismissed with prejudice.

6. MMWA Claims

a. Arguments and Allegations

Defendants assert that the counts for violation of the MMWA in the CCCAC and CTPPCC must be dismissed because those counts require a valid state-law warranty claim to serve as an "anchor," and none of Plaintiffs' state-law warranty claims are valid because they are pre-empted. DE 1582 at 10, 39. In addition, the MMWA does not apply to FDA-regulated product labeling. *Id.* at 10, 39-40.

Plaintiffs do not dispute that their claims under the MMWA require a valid state-law warranty claim. *See* DE 2499 at 63-64 (argument of Plaintiffs that they have valid

[10] The Court notes again, however, that some of the parties categorized as Generic Manufacturer Defendants are also categorized as Repackager Defendants. *See, e.g.*, CCCAC ¶¶ 280, 288.

express-warranty and implied-warranty claims to serve as a MMWA "anchor"). Plaintiffs argue, however, that their state-law warranty claims are valid because they are not pre-empted. DE 2010-1 at 40. If the Court concludes at this stage that the MMWA does not apply to written warranties arising from FDA-regulated product labeling, Plaintiffs still can pursue their claims for breach of implied warranties under the MMWA. *Id.* at 40-41.

Plaintiffs allege in their MMWA counts that Defendants expressly warranted that ranitidine products "were safe for human consumption and fit to be used for their intended purpose" and that Defendants impliedly warranted that the products "were of merchantable quality and safe and fit for their intended use." *See, e.g.*, CCCAC ¶¶ 810, 814; CTPPCC ¶¶ 595, 599. Defendants breached these warranties because ranitidine products were dangerous in that they contained cancer-causing levels of NDMA. *See, e.g.*, CCCAC ¶¶ 811, 813, 817; CTPPCC ¶¶ 596, 598, 602.

b. The MMWA

The MMWA provides a private cause of action for "a consumer who is damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation . . . under a written warranty, implied warranty, or service contract." 15 U.S.C. § 2310(d)(1). A "supplier" is "any person engaged in the business of making a consumer product directly or indirectly available to consumers," and a "warrantor" is "any supplier or other person who gives or offers to give a written warranty or who is or may be obligated under an implied warranty." *Id.* § 2301(4), (5). The MMWA defines the phrase "written warranty" as

> (A) any written affirmation of fact or written promise made in connection with the sale of a consumer product by a supplier to a buyer which relates to the nature of the material or workmanship and affirms or promises that such material or workmanship is defect free or will meet a specified level of performance over a specified period of time, or
>
> (B) any undertaking in writing in connection with the sale by a supplier of a consumer product to refund, repair, replace, or take other remedial action with

> respect to such product in the event that such product fails to meet the specifications set forth in the undertaking,
>
> which written affirmation, promise, or undertaking becomes part of the basis of the bargain between a supplier and a buyer for purposes other than resale of such product.

Id. § 2301(6). The phrase "implied warranty" means "an implied warranty arising under State law . . . in connection with the sale by a supplier of a consumer product." *Id.* § 2301(7); *see Barabino v. Dan Gamel, Inc.*, No. 2:04-cv-2359-MCE-PAN, 2006 WL 2083257, at *4 (E.D. Cal. July 25, 2006) (explaining that "courts must look to the relevant state law to determine the meaning and creation of any implied warranty" when applying the MMWA).

A plaintiff's claim under the MMWA is viable only if the plaintiff also has stated a valid breach-of-warranty claim under state law. *See Cardenas v. Toyota Motor Corp.*, 418 F. Supp. 3d 1090, 1110-11 (S.D. Fla. 2019) (explaining that, "[t]o state a claim under the Magnuson-Moss Warranty Act, . . . a plaintiff must also state a valid breach of warranty claim"); *Melton v. Century Arms, Inc.*, 243 F. Supp. 3d 1290, 1304 (S.D. Fla. 2017) (explaining that "a Magnuson-Moss Warranty Act claim only exists if a valid breach of warranty claim is also stated").

The MMWA is "inapplicable to any written warranty the making or content of which is otherwise governed by Federal law." 15 U.S.C. § 2311(d). "If only a portion of a written warranty is so governed by Federal law, the remaining potion shall be subject to" the MMWA. *Id.* Applying § 2311(d), federal courts have held that the MMWA is inapplicable to both express-warranty and implied-warranty claims for products with FDA-regulated labeling. *See, e.g., Hernandez v. Johnson & Johnson Consumer Inc.*, No. 3:19-cv-15679-BRM-TJB, 2020 WL 2537633, at *5 (D.N.J. May 19, 2020) (concluding that the MMWA "is inapplicable to any alleged express or implied warranty claims on the labeling of" pain relievers); *Dopico v. IMS Trading Corp.*, No. 3:14-cv-1874-BRM-DEA, 2018 WL 4489677, at *6 (D.N.J. Sept. 18, 2018) (concluding that

the MMWA "is inapplicable to any alleged express or implied warranty claims on the labeling of" FDA-regulated dog treats); *Jasper v. MusclePharm Corp.*, No. 14-cv-02881-CMA-MJW, 2015 WL 2375945, at *1, 5-6 (D. Colo. May 15, 2015) (adopting a Report and Recommendation to dismiss a MMWA claim under § 2311(d) where the plaintiff had brought express-warranty and implied-warranty claims related to weight-loss supplements and citing multiple cases as reaching the conclusion that "the label of the product at issue is 'governed' under the FDCA, and therefore the Magnuson-Moss Warranty Act is 'inapplicable'").[11]

c. Analysis and Conclusion

As discussed in Section VII.C.1.e. of this Order, the Court is dismissing all counts against Defendants, including the counts for breach of express and implied warranties. The Court therefore dismisses the MMWA counts, as a MMWA claim requires a valid breach-of-warranty claim. *See Cardenas*, 418 F. Supp. 3d at 1110-11; *Melton*, 243 F. Supp. 3d at 1304.

Should Plaintiffs replead any express-warranty or implied-warranty claims and replead MMWA claims, the MMWA is inapplicable to warranty claims based on language on drug labeling that the FDA governs and that falls within the definition of "written warranty." *See* 15 U.S.C. § 2311(d) (providing that the MMWA is "inapplicable to any written warranty the making or content of which is otherwise governed by Federal law"). To the extent that Plaintiffs maintain that they can pursue written warranty claims under the MMWA based on any language that the FDA does not govern, they have failed to plead a plausible claim under the MMWA

[11] Plaintiffs cite a single case to support their argument that they can pursue claims for breach of implied warranties under the MMWA. *See* DE 2010-1 at 41. That case, *Forcellati v. Hyland's Inc.*, concluded that the plaintiffs had not identified language on the labeling of homeopathic remedies that fell within the definition of "written warranty" under the MMWA, but that the plaintiffs were entitled to a trial on their claim of breach of implied warranty under the MMWA. No. CV 12-1983-GHK, 2015 WL 9685557, at *6 (C.D. Cal. Jan. 12, 2015). *Forcellati* is distinguishable because the FDA does not approve the labeling for homeopathic remedies. Plaintiffs have not cited any authority to support a departure from caselaw specific to the drug context that has held that the MMWA is inapplicable to both express-warranty and implied-warranty claims. *See Hernandez*, 2020 WL 2537633, at *5.

because they have not specified the relevant language that they assert meets the MMWA's definition of "written warranty." *See id.* (explaining that, "[i]f only a portion of a written warranty is so governed by Federal law, the remaining portion shall be subject to this chapter"); *see also id.* § 2301(6) (defining the phrase "written warranty"); *Viggiano v. Hansen Nat. Corp.*, 944 F. Supp. 2d 877, 898 (C.D. Cal. 2013) (dismissing a MMWA claim because the challenged language on product labeling did not create a written warranty within the definition in the MMWA). To the extent that Plaintiffs still maintain that they can pursue implied-warranty claims under the MMWA, they should be prepared to explain whether their implied-warranty claims arise from anything other than the drug labeling. The MMWA count in the CCCAC, Count 3, against Defendants and the MMWA count in the CTPPCC, Count 4, against Generic Manufacturer Defendants are dismissed without prejudice and with leave to amend.

7. Absolute Liability

In their Opposition to the Motion to Dismiss, Plaintiffs "incorporate by reference the Retailer, Pharmacy, and Distributor opposition, which refutes the Repackager Defendants' arguments." DE 2010-1 at 41. By that statement, the Court presumes that Plaintiffs mean to incorporate their arguments about absolute liability in their Opposition to Distributor, Retailer, and Pharmacy Defendants' Rule 12 Motions to Dismiss on Preemption Grounds. *See* DE 1977 at 12-17. Defendants reply that Plaintiffs have failed to show that any state has adopted an absolute liability framework for repackagers. DE 2133 at 7-8, 22. Defendants further argue that, if a state were to adopt such a framework, the state's law would directly conflict with federal law. *Id.* at 22.

The Court's discussion and analysis of absolute liability is included within the Order Granting Retailer and Pharmacy Defendants' Rule 12 Motion to Dismiss on the Ground of Preemption, Granting Distributor Defendants' Rule 12 Motion to Dismiss on the Ground of

Preemption, Denying as Moot Retailer and Pharmacy Defendants' Rule 12 Motion to Dismiss on State Law Grounds, and Denying as Moot Distributor Defendants' Rule 12 Motion to Dismiss on Various Group-Specific Grounds. For the reasons given in that Order, any claims against Repackager Defendants that rely on absolute liability are dismissed with prejudice.

8. Derivative Counts

Counts XIII, XIV, and XV of the MPIC are claims for loss of consortium, damages to be paid to the estates of deceased ranitidine-product consumers, and wrongful death. MPIC ¶¶ 637-56. Defendants refer to these three counts as "derivative" claims and argue that these claims must be dismissed if all of the other claims against them are dismissed. DE 1582 at 37-38. Plaintiffs do not dispute that the derivative claims must be dismissed if no other claims remain against Defendants, but Plaintiffs assert again that they can proceed with all of their claims against Defendants. DE 2010-1 at 39; *see In re Darvocet*, 756 F.3d at 936 (affirming a district court's dismissal of "derivative claims for wrongful death, survivorship, unjust enrichment, loss of consortium, and punitive damages" when the district court had dismissed all "underlying claims" because the derivative claims "stand or fall with the underlying claims on which they rest"). Because the Court is dismissing all underlying claims against Defendants for the reasons given herein, the derivative claims raised against Defendants in Counts XIII, XIV, and XV of the MPIC are dismissed without prejudice.

9. Express Pre-emption Under 21 U.S.C. § 379r

Defendants' Motion to Dismiss incorporates by reference the arguments about express pre-emption that Brand-Name Manufacturer Defendants make in their motion to dismiss based on pre-emption. DE 1582 at 38-39; *see* DE 1580. In that motion to dismiss, Brand-Name Manufacturer Defendants contend that 21 U.S.C. § 379r prohibits Plaintiffs from obtaining

damages in the form of refunds for the purchase of OTC ranitidine products. DE 1580 at 7, 14-22; *see* 21 U.S.C. § 379r(a) (providing that "no State or political subdivision of a State may establish or continue in effect any requirement . . . that is different or in addition to, or that is otherwise not identical with, a requirement under this chapter"). The Court will address § 379r in a forthcoming Order on Branded Defendants' Rule 12 Partial Motion to Dismiss Plaintiffs' Three Complaints as Preempted by Federal Law.

VIII. Conclusion

For the foregoing reasons, it is **ORDERED AND ADJUDGED** that Defendant Generic Manufacturers' and Repackagers' Rule 12 Motion to Dismiss on the Ground of Preemption [DE 1582] is **GRANTED.**

1. Plaintiffs' claims based on alleged product and labeling defects that Defendants could not independently change while remaining in compliance with federal law are **DISMISSED WITH PREJUDICE** consistent with this Order. Because all of Plaintiffs' counts against Defendants in the Master Complaints incorporate such allegations, all counts against Defendants are **DISMISSED**.

2. Plaintiffs' claims against Repackager Defendants that rely on absolute liability are **DISMISSED WITH PREJUDICE** consistent with this Order.

3. Plaintiffs are granted leave to replead claims against Defendants based on expiration dates, testing, storage and transportation conditions, warning the FDA, manufacturing defects, and the MMWA, as well as to replead their derivative counts, consistent with this Order.

4. Under Pretrial Order # 36, Plaintiffs' repled Master Complaints are due 30 days after the Court issues its Order on Article III standing. DE 1346 at 4. The Court **AMENDS** that requirement in Pretrial Order # 36. Plaintiffs' repled Master Complaints are due 30 days after the

Court issues its forthcoming Order on Branded Defendants' Rule 12 Partial Motion to Dismiss Plaintiffs' Three Complaints as Preempted by Federal Law. DE 1580. All other requirements in Pretrial Order # 36 remain in place.

DONE and ORDERED in Chambers, West Palm Beach, Florida, this 31st day of December, 2020.

ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE